REMARKS/ARGUMENTS

Claims 1-37 are pending in the application.

Claims 1 to 7, 12, 13, 19, 20 to 25, 30 and 31 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Solem et al. (US Patent No. 6,210,432) in view of Oz et al. (US Patent No. 6,269,819).

Applicants have amended claim 1 to recite manipulating the prosthesis to a second configuration different from the first configuration to exert a compressive force against the mitral valve annulus to reduce mitral valve regurgitation, monitoring the degree of regurgitation while the prosthesis is in the second configuration, and adjusting the prosthesis to a third configuration different from the second configuration in response to the monitoring step. In contrast, Solem et al. and Oz et al. fail to teach or suggest the three configurations of the prosthesis as recited in claim 1 and the adjustment of the prosthesis to the third configuration in response to the monitoring step.

Referring to Solem et al., and in particular to FIGS. 12 and 13, in a first state of the elongate body, the stents 23, 24 and 25 of the elongate body are inserted in the coronary sinus. In the second state of the elongate body, the wires 26 and 27 are maneuvered in order for the elongate body to press against the mitral valve annulus 6 and close the gap 20 of the mitral valve. However, after the elongate body is in the second state, Solem et al. neither carries out a monitoring step as recited in claim 1, nor carries out an adjusting step after the monitoring step in order to adjust the elongate body to a third state in response to the monitoring step.

Oz et al. also fails to teach or suggest adjusting a prosthesis to a third configuration different from the second configuration in response to a monitoring step.

Oz et al., is directed to a grasper and fasteners by which the mitral valve is repaired. Referring to FIG. 1, the method of repairing the mitral valve is disclosed as including the steps of bringing the anterior and posterior leaflets of the mitral valve together with the grasper 16 and then fastening the leaflets with a fastener. Oz et al., discloses performing the noted method by

open chest surgery (see col. 7, lines 39-67), thorascopically (see col. 8, lines 1-18), or percutaneously (see col. 8, lines 19-31).

In rejecting the claims, the Examiner asserts on page 2 of the Office action that Oz et al. discloses monitoring hemodynamic function before the adjustment for the purpose of allowing the surgeon to control the bleeding. In support of the assertion, the Examiner refers to col. 8, lines 1-18 and col. 9, lines 33-43 of Oz et al. Applicants respectfully submit that the portions of Oz et al. to which the Examiner refers do not support such an assertion. Furthermore, Applicants submit that Oz et al. does not teach or suggest adjusting any feature of the grasper 16 or the method by which the grasper 16 is used in response to monitoring of hemodynamic function.

Oz et al., discloses the following at col. 8 lines 1-18 regarding the thorascopic method:

> Third, such a procedure can be undertaken thorascopically. The patient is intubated selectively in order to collapse the left lung, and percutaneous ports are inserted in to the left chest allowing visualization of the apex of the heart or left atrium. Through a separate port, the device is introduced into the thoracic cavity and subsequently into the left ventricle through the apex. Previously, a purse-string or triangular suture had been placed around the tip of the ventricle to control bleeding around the ventricular entry site. Subsequent steps of the repair are identical to those described for patients with an open chest, off bypass.
>
> Should the operation require the patient to be placed on bypass, this can be attained percutaneously from the groin by cannulating the femoral artery and vein. This technique could prove particularly useful in the early stages of development of the technique, since the surgeon would be able to operate on a decompressed heart and slow or cease the heart rate as needed, without hemodynamic compromise.

(Emphasis added).

As disclosed in the above-quoted portion of Oz et al., the control of bleeding to which the Examiner refers concerns the bleeding at a site where the grasper is introduced into the thoracic cavity. The entry site is sutured to control the bleeding. Furthermore, the above-quoted portion of Oz et al. does not describe monitoring hemodynamic function as the Examiner asserts. The only reference to any hemodynamic function concerns the surgeon placing a patient on bypass in order to cease the heart rate if needed without hemodynamic compromise. Therefore, in contrast

to the Examiner's assertion, Oz et al. does not monitor hemodynamic function to adjust any feature of the grasper 16 or the method by which the grasper 16 is used in response to monitoring of hemodynamic function.

Referring to col. 9, lines 19-43, Oz et al. discloses that mitral valve repair in accordance with its disclosed method were performed on eleven patients. However, prior to performing the disclosed method, preoperative hemodynamics were obtained to diagnose mitral valve regurgitation of each patient. Therefore, in contrast to the Examiner's assertion, Oz et al. does not teach or suggest adjusting any feature of the grasper 16 or the method by which the grasper 16 is used in response to the monitoring of hemodynamic function. Rather, the monitoring of hemodynamic function in Oz et al. was performed in order to asses mitral valve regurgitation prior to applying the method and using the device disclosed in Oz et al.

Based on the foregoing, Applicants submit that both Solem et al. and Oz et al. fail to teach or suggest monitoring the degree of regurgitation while the prosthesis is in the second configuration, and adjusting the prosthesis to a third configuration different from the second configuration in response to the monitoring step, as recited in claim 1. Therefore, claims 1 to 7, 12, 13, 20 to 25, 30 and 31 are patentable over Solem et al., in view of Oz et al.

Claim 19 has been amended to recite manipulating the prosthesis from the first configuration toward a second configuration for exerting a compressive force against the mitral valve annulus to reduce mitral valve regurgitation, monitoring the degree of regurgitation while manipulating the prosthesis from the first configuration toward the second configuration, and fixing the prosthesis in the second configuration in response to the monitoring step. In contrast, Solem et al. and Oz et al. fail to teach or suggest the noted limitations of claim 19.

As discussed in the foregoing, Solem et al. fails to teach or suggest monitoring the degree of regurgitation and fixing the prosthesis based on the monitoring step. Furthermore, as discussed in the foregoing, Oz et al. does not monitor the degree of regurgitation while manipulating its grasper 16 or the fastener for fastening the valve leaflets, and then fixing the valve leaflets with the fastener in response to a monitoring step. Therefore, Solem et al. and Oz

et al. fail to teach or suggest monitoring the degree of regurgitation while manipulating the prosthesis from the first configuration toward the second configuration and fixing the prosthesis in the second configuration in response to the monitoring step, as recited in claim 19. Accordingly, claim 19 is patentable over Solem et al., in view of Oz et al.

Claims 8 to 11 and 26 to 29 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Solem et al. in view of Oz et al. in further view of Wright (US Patent No. 5,522,884). Claims 14 and 32 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Solem et al. in view of Oz et al. in further view of Fowler, Jr. et al. (US Patent No. 5,086,776). Claims 15 and 33 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Solem et al. in view of Oz et al. in further view of Killman (US Patent No. 5,846,198). Claims 16 and 34 have rejected under 35 U.S.C. 103(a) as being unpatentable over Solem et al. in view of Oz et al. in further view of Mehta (US Patent No. 5,476,453). Claims 17 and 35 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Solem et al. in view of Oz et al. in further view of McIntyre (US Patent No. 5,291,895). Claims 18, 36, and 37 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Solem et al. in view of Oz et al. in further view of Kadhiresan (US Patent No. 5,935,081). Because claims 1 and 19 are patentable over Solem et al., and Oz et al., Applicants submit that the above rejected claims are also patentable.

Consideration and allowance of the claims are respectfully requested.

Respectfully submitted,
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